

Amendments to the Claims:

Claim 1 (Currently Amended): A pharmaceutical composition comprising a short acting hypnotic or a salt thereof contained in two pharmaceutical entities, one immediate release entity and one delayed release entity, adapted to release the short acting hypnotic over a predetermined time period, according to an *in vitro* profile of dissolution, comprising two release pulses, the first being immediate and the second being delayed by a fixed time after the administration wherein the delayed release entity contains a cationic or zwitterionic surfactant and an organic acid and is coated with an ammonio methacrylate copolymer.

Claim 2 (Previously amended): A pharmaceutical composition according to claim 1, wherein the first pulse has a maximum duration of 30 minutes.

Claim 3 (Previously amended): A pharmaceutical composition according to claim 1 wherein the fixed time is between 50 and 200 minutes.

Claim 4 (Previously amended): A pharmaceutical composition according to claim 3 wherein the fixed time is between 60 and 150 minutes.

Claim 5 (Previously amended): A pharmaceutical composition according to claim 1 wherein 40 to 70% of the total amount of the short acting hypnotic is released during the immediate release pulse.

Claim 6 (Previously amended): A pharmaceutical composition according to claim 1 wherein the delayed release pulse lasts between 30 and 200 minutes.

Claim 7 (Previously amended): A pharmaceutical composition according to claim 1 wherein the time for release of 85% of the total amount of the short acting hypnotic is between 2 and 6 hours.

Claim 8 (Cancelled)

Claim 9 (Currently amended): A pharmaceutical composition according to ~~claim 8 as claim 1~~ as a dosage form selected from the group consisting of capsules, tablets, multilayer tablets, multicoated tablets.

Claim 10 (Currently amended): A pharmaceutical composition according to ~~claim 8 as claim 1~~ as a capsule comprising one or more immediate release tablets and one or more delayed release tablets.

Claim 11 (Currently amended): A pharmaceutical composition according to ~~claim 8 as claim 1~~ as a capsule comprising a mixture of delayed release particles and immediate release particles.

Claim 12 (Currently amended): A pharmaceutical composition according to ~~claim 8 as claim 1~~ as a capsule comprising a mixture of delayed release particles and an immediate release powder.

Claim 13 (Currently amended): A pharmaceutical composition according to ~~claim 8 as claim 1~~ as a tablet comprising a number of delayed release coated pellets comprising the short-acting hypnotic imbedded in a matrix.

Claim 14 (Previously amended): A pharmaceutical composition according to claim 10 wherein the delayed release tablets are coated with at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

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Claim 15 (cancelled)

Claim 16 (Previously amended): A pharmaceutical composition according to claim 14 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claims 17-18 (cancelled)

Claim 19 (Currently amended): A pharmaceutical composition according to ~~claim 8~~ claim 1 wherein the immediate release entity and the prolonged release entity are administered simultaneously but separately.

Claim 20 (Currently amended): A pharmaceutical composition according to ~~claim 8~~ claim 1 wherein the delayed release entity comprises a pharmaceutically acceptable organic acid selected from the group consisting of tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their salts, in the form of racemates or isomers.

Claim 21 (Previously amended): A pharmaceutical composition according to claim 1 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.


Claim 22 (Previously amended): A pharmaceutical composition according to claim 21 wherein the short acting hypnotic is chosen from triazolam, temazepam, brotizolam, zolpiclone, (R)-zopiclone, zaleplon, alimemazine, zolpidem and pharmaceutically acceptable salts thereof.

Claim 23 (Previously amended): A pharmaceutical composition according to claim 22 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

Claims 24-25 (cancelled)

Claim 26 (Previously amended): A pharmaceutical composition according to claim 73 wherein the visual change is chosen from a change in color, floating of the composition at the surface of the drink, and formation of insoluble particles on the surface of the drink, on the brim of the glass, in the drink and/or on the bottom of the glass or a combination thereof.

Claim 27 (Previously presented): A pharmaceutical composition according to claim 2 wherein the fixed time is between 60 and 150 minutes.

Claim 28 (Previously presented): A pharmaceutical composition according to claim 27 wherein the second pulse lasts between 30 and 200 minutes.

Claim 29 (Previously presented): A pharmaceutical composition according to claim 28 wherein the 40 to 70% of the total amount of short-acting hypnotic is released during the immediate release pulse.

Claim 30 (Previously presented): A pharmaceutical composition according to claim 29 wherein the time for release of 85% of the total amount of short-acting hypnotic is between 2 and 6 hours.

Claim 31 (Previously presented): A pharmaceutical composition according to claim 13 wherein the matrix comprises the short-acting hypnotic.

Claim 32 (Previously presented): A pharmaceutical composition according to claim 13 wherein immediate release non-coated pellets are mixed with delayed release coated pellets.

Claim 33 (Previously presented): A pharmaceutical composition according to claim 13 wherein the delayed release coated pellets are further coated with a layer comprising the short-acting hypnotic imbedded in a matrix free from said short-acting hypnotic.

Claim 34 (Previously presented): A pharmaceutical composition according to claim 13 as a tablet comprising one or more layers containing the delayed release pellets in a matrix free from the short-acting hypnotic and one or more layers containing the short-acting hypnotic in an immediate release matrix.

Claim 35 (Previously presented): A pharmaceutical composition according to claim 11 wherein the delayed release particles are coated with a mixture containing at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

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Claim 36 (Previously presented): A pharmaceutical composition according to claim 13 wherein the delayed release pellets are coated with at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

Claim 37 (Previously presented): A pharmaceutical composition according to claim 31 wherein the delayed release pellets are coated with at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

Claim 38 (Previously presented): A pharmaceutical composition according to claim 32 wherein the delayed release pellets are coated with at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

Claim 39 (Previously presented): A pharmaceutical composition according to claim 33 wherein the delayed release pellets are coated with at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

Claim 40 (Previously presented): A pharmaceutical composition according to claim 34 wherein the delayed release pellets are coated with at least one ammonio methacrylate copolymer and the core contains a cationic or zwitterionic surfactant.

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Claim 41 (Previously presented): A pharmaceutical composition according to claim 35 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claim 42 (Previously presented): A pharmaceutical composition according to claim 36 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the

group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claim 43 (Previously presented): A pharmaceutical composition according to claim 37 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claim 44 (Previously presented): A pharmaceutical composition according to claim 38 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claim 45 (Previously presented): A pharmaceutical composition according to claim 39 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

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Claim 46 (Previously presented): A pharmaceutical composition according to claim 40 wherein the cationic surfactant is selected from the group consisting of trimethyl-dimyristoyl-ammonium propionate, dimethyl-dioctadecyl-ammonium bromide, trimethyl-cetyl-ammonium bromide, dimethyl-didodecyl-ammonium bromide, benzalkonium chloride, cetylpyridinium chloride and cetrimide and the zwitterionic surfactant is selected from the

group consisting of N-alkylbetaines, C-alkylbetaines, N-alkylamidobetaines, N-alkylglycines, phosphatidylcholines and lecithins.

Claim 47 (Previously presented): A pharmaceutical composition according to claim 16 wherein the core contains cocamidopropylbetaine.

Claim 48 (Previously presented): A pharmaceutical composition according to claim 41 wherein the core contains cocamidopropylbetaine.

Claim 49 (Previously presented): A pharmaceutical composition according to claim 42 wherein the core contains cocamidopropylbetaine.

Claim 50 (Previously presented): A pharmaceutical composition according to claim 43 wherein the core contains cocamidopropylbetaine.

Claim 51 (Previously presented): A pharmaceutical composition according to claim 44 wherein the core contains cocamidopropylbetaine.

Claim 52 (Previously presented): A pharmaceutical composition according to claim 45 wherein the core contains cocamidopropylbetaine.

Claim 53 (Previously presented): A pharmaceutical composition according to claim 46 wherein the core contains cocamidopropylbetaine.

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Claim 54 (Previously presented): A pharmaceutical composition according to claim 35 wherein the delayed release entity comprises a pharmaceutical acceptable organic acid selected from the group consisting of tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their salts, in the form of racemates or isomers.

Claim 55 (Previously presented): A pharmaceutical composition according to claim 36 wherein the delayed release entity comprises a pharmaceutical acceptable organic acid selected from the group consisting of tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their salts, in the form of racemates or isomers.

Claim 56 (Previously presented): A pharmaceutical composition according to claim 41 wherein the delayed release entity comprises a pharmaceutical acceptable organic acid selected from the group consisting of tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their salts, in the form of racemates or isomers.

Claim 57 (Previously presented): A pharmaceutical composition according to claim 42 wherein the delayed release entity comprises a pharmaceutical acceptable organic acid selected from the group consisting of tartaric, malic, fumaric, lactic, citric, adipic or succinic acid and their salts, in the form of racemates or isomers.

Claim 58 (Currently amended): A pharmaceutical composition according to ~~claim 8~~ claim 1 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.

Claim 59 (Previously presented): A pharmaceutical composition according to claim 13 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.

Claim 60 (Previously presented): A pharmaceutical composition according to claim 30 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.

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Claim 61 (Previously presented): A pharmaceutical composition according to claim 36 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.

Claim 62 (Previously presented): A pharmaceutical composition according to claim 42 wherein the short acting hypnotic belongs to the therapeutic classes of benzodiazepines, cyclopyrrolones, pyrazolopyrimidines, phenothiazines or imidazopyridines.

Claim 63 (Previously presented): A pharmaceutical composition according to claim 58 wherein the short acting hypnotic is chosen from triazolam, temazepam, brotizolam,

zolpiclone, (R)-zopiclone, zaleplon, alimemazine, zolpidem and pharmaceutically acceptable salts thereof.

Claim 64 (Previously presented): A pharmaceutical composition according to claim 59 wherein the short acting hypnotic is chosen from triazolam, temazepam, brotizolam, zolpiclone, (R)-zopiclone, zaleplon, alimemazine, zolpidem and pharmaceutically acceptable salts thereof.

Claim 65 (Previously presented): A pharmaceutical composition according to claim 60 wherein the short acting hypnotic is chosen from triazolam, temazepam, brotizolam, zolpiclone, (R)-zopiclone, zaleplon, alimemazine, zolpidem and pharmaceutically acceptable salts thereof.

Claim 66 (Previously presented): A pharmaceutical composition according to claim 61 wherein the short acting hypnotic is chosen from triazolam, temazepam, brotizolam, zolpiclone, (R)-zopiclone, zaleplon, alimemazine, zolpidem and pharmaceutically acceptable salts thereof.

Claim 67 (Previously presented): A pharmaceutical composition according to claim 62 wherein the short acting hypnotic is chosen from triazolam, temazepam, brotizolam, zolpiclone, (R)-zopiclone, zaleplon, alimemazine, zolpidem and pharmaceutically acceptable salts thereof.

Claim 68 (Previously presented): A pharmaceutical composition according to claim 63 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

Claim 69 (Previously presented): A pharmaceutical composition according to claim 64 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

Claim 70 (Previously presented): A pharmaceutical composition according to claim 65 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

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Claim 71 (Previously presented): A pharmaceutical composition according to claim 66 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

Claim 72 (Previously presented): A pharmaceutical composition according to claim 67 wherein the short acting hypnotic is zolpidem or a pharmaceutically acceptable salt thereof.

Claim 73 (Previously presented): A pharmaceutical composition according to claim 1 additionally comprising a constituent which, upon introduction of the composition into an alcoholic or non-alcoholic drink, causes a visual change in the appearance of the drink.

Claim 74 (Previously presented): A pharmaceutical composition according to claim 13 additionally comprising a constituent which, upon introduction of the composition into an alcoholic or non-alcoholic drink, causes a visual change in the appearance of the drink.

Claim 75 (Previously presented): A pharmaceutical composition according to claim 74 wherein the visual change is chosen from a change in color, floating of the composition at the surface of the drink, and formation of insoluble particles on the surface of the drink, on the brim of the glass, in the drink and/or on the bottom of the glass or a combination thereof.

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